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Proposed Registration Decision PRD2011-03

Liquid Corn Gluten

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Overview

Proposed Registration Decision for Liquid Corn Gluten

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and its Regulations, is proposing full registration for the sale and use of Liquid Corn Gluten Manufacturing Concentrate and TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer, containing the active ingredient Liquid Corn Gluten, as a pre-emergent dandelion, crabgrass (smooth and large) and white clover seed germination inhibitor for use on lawns where established perennial ryegrass and Kentucky bluegrass are the predominant grass species.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Liquid Corn Gluten Manufacturing Concentrate and TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Product Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on Liquid Corn Gluten, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on Liquid Corn Gluten, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments. For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Liquid Corn Gluten?

Liquid corn gluten is the active ingredient contained in the end-use product TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer at a concentration of 99.81%. TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer is a pre-emergent dandelion, crabgrass (smooth and large) and white clover seed germination inhibitor for use on lawns where established perennial ryegrass and Kentucky bluegrass are the predominant grass species.

Health Considerations

Can Approved Uses of Liquid Corn Gluten Affect Human Health?

Potential exposure to liquid corn gluten may occur when handling and applying the end-use product or when people enter a recently treated site. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The active ingredient, liquid corn gluten, is expected to be of low acute toxicity via the oral, dermal and pulmonary routes, minimally irritating to the skin, mildly irritating to the eyes, and a potential sensitizer. Therefore, precautionary statements alerting users to the eye irritation and sensitization potential of liquid corn gluten are required on the labels for Liquid Corn Gluten Manufacturing Concentrate and TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Limited toxicology information was available for liquid corn gluten. However, information available on corn gluten meal, which is the starting material for processing liquid corn gluten, did not indicate hazards that would be expected with liquid corn gluten.

The data requirements for acute toxicity, short-term toxicity, irritation and sensitization potential, prenatal developmental toxicity and genotoxicity studies were waived by the PMRA based on toxicological information on the starting material of corn gluten meal, widespread use in the food industry of the hydrolyzation enzyme used in the manufacture of liquid corn gluten, as well as the existing food and cosmetic uses of hydrolyzed corn gluten without any reported adverse effects.

Risk to humans from domestic use of TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer is not expected to be of concern due to the low toxicity of the formulation and additional precautionary measures on the label that are aimed at mitigating exposure, including restrictions on re-entry to treatment sites and the wearing of personal protective equipment (PPE).

Residues in Water and Food

Dietary risks from liquid corn gluten on food and water are not of concern.

TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer is for herbicidal use on domestic lawns, and is not intended for use on food crops.

No risk due to exposure from drinking water is anticipated as liquid corn gluten, by its organic nature, is expected to degrade rapidly in the environment and is not likely to be persistent.

Risks From Handling Liquid Corn Gluten

Risks are not of concern when Liquid Corn Gluten is used according to label directions, which include protective measures.

Residential exposure to individuals mixing, loading, or applying TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer is not expected to result in unacceptable risk when the product is used according to label directions.

Accidental bystander exposure is possible from spray drift, but exposure is expected to be negligible if the precautionary label statements are observed by the domestic users.

Precautionary (for example, wearing of personal protective equipment) and general hygiene statements on the label of TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer are considered adequate to protect individuals, children and pets from domestic use of this product.

Environmental Considerations

What Happens When Liquid Corn Gluten Is Introduced Into the Environment?

Liquid corn gluten is an hydrolyzate of corn gluten meal, a naturally occurring substance in the environment. The use of liquid corn gluten is not expected to cause any adverse environmental effects to non-target organisms.

As the protein in liquid corn gluten is already partially broken down, it is expected that further degradation of liquid corn gluten will occur in the environment. Given the known history of use of corn gluten meal and the limited exposure expected from residential turf use, the risk to non-target organisms to liquid corn gluten in the end-use product TurfMaize Bio-Herbicide Corn Gluten Weed Preventer is considered to be negligible, and the use of this end-use product is not expected to cause any adverse effects to the environment.

Value Considerations

What Is the Value of TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer?

TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer contains liquid corn gluten at a concentration of 99.81%. TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer is a water-soluble material containing an active ingredient that is derived from an active ingredient present in the registered corn gluten meal products. It is a non-conventional herbicide for use on lawns where established perennial ryegrass and Kentucky bluegrass are the predominant grass species. TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer may inhibit dandelion, crabgrass (smooth and large) and white clover seed germination when used in conjunction with a sound lawn-maintenance program.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures on the technical and end-use product labels to address the potential risks identified in this assessment are as follows:

The signal words "POTENTIAL SENSITIZER" and "CAUTION EYE IRRITANT" and the statement "May cause sensitization" are present on the principal and the secondary display panels, respectively, on the labels for Liquid Corn Gluten Manufacturing Concentrate and TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer.

Both the technical and end-use product labels include additional precautionary statements, including "Avoid contact with skin, eyes or clothing," "May irritate eyes and skin," "May cause sensitization," and "May cause respiratory irritation." Also, the labels include the precautionary statements "Avoid breathing vapours" and "Avoid breathing spray mist" on the technical and the end-use product labels, respectively.

The TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer label also instructs users to not apply the end-use product if a member of the household has a sensitivity or allergy to corn, and not to apply under windy conditions.

As a general hygiene measure, the TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer label requires users to wear a long-sleeve shirt, long pants, closed foot wear and gloves when handling the end-use product and during application. Also, the label instructs users to avoid contact of the product with the skin, eyes or clothing. As a further hygiene measure, freshly prepared spray solution is to be used each time when using a hand-held or backpack sprayer.

To prevent post-application exposure of adults, children and pets, the TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer label includes the restricted-entry statement, "Do not re-enter or allow re-entry of adults, children or pets into treated areas until the spray is dried."

Environment

No additional risk mitigation measures or label statements are required.

Next Steps

Before making a final registration decision on liquid corn gluten, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration deci[illegible] it will publish a Registration Decision on liquid corn gluten (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Liquid Corn Gluten Manufacturing Concentrate

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Liquid Corn Gluten
Function	Herbicide
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	Not applicable
2. **Chemical Abstracts Service (CAS)**	Not applicable
CAS number	Not applicable
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient	100%

1.2 Physical and Chemical Properties of the Active Ingredient and End-use Product

Technical Product—Liquid Corn Gluten Manufacturing Concentrate

Property	Result
Colour and physical state	Yellow
Odour	Corn odour
Melting range	Not applicable
Boiling point or range	Not applicable
Density	1.16 g/cm^3
Vapour pressure at 20°C	Not applicable
Henry's law constant at 20°C	
Ultraviolet (UV)-visible spectrum	Not applicable
Solubility in water at 20°C	Insoluble in water
Solubility in organic solvents at 20°C (g/100 mL)	Not applicable
n-Octanol–water partition coefficient (K_{ow})	Not applicable
Dissociation constant (pK_a)	Not applicable
Stability (temperature, metal)	Not applicable

End-use Product—TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer

Property	Result
Colour	Yellow
Odour	Corn odour
Physical state	Liquid
Formulation type	Liquid
Guarantee	99.81%
Container material and description	High Density Polyethylene Plastic bottles, 1L to 10L
Density	1.16 g/cm^3
pH of 1% dispersion in water	4–5
Oxidizing or reducing action	Not applicable
Storage stability	Stable for 12 months when stored in HPDE commercial packaging at ambient temperature.
Corrosion characteristics	Stable and no corrosion for 12 months when stored in HPDE commercial packaging at ambient temperature
Explodability	The product does not contain potentially explosive components.

1.3 Directions for Use

1.3.1 TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer

TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer is a pre-emergent dandelion, crabgrass (smooth and large) and white clover seed germination inhibitor for use on lawns where established perennial ryegrass and Kentucky bluegrass are the predominant grass species. The end-use product is recommended for application in the early spring at a rate of 1.08 L of product per $100m^2$ (1.25 kg a.i./$100m^2$) and a second application in the late summer or early fall (after heat stress has passed) at a rate of 1.08 L of product per $100m^2$ (1.25 kg a.i./$100m^2$).

Where the end-use product is available for hose-end attachment or available for a hand-held or backpack sprayer, follow the label instructions and direct the spray over the lawn surface in a sweeping side-to-side movement. Do not overlap areas already treated. The area of the lawn surface treated will vary on the size of product container.

The label also includes a number of cautionary statements relating to the conditions of application:

- Apply to mature lawns having a well developed root mass.
- Do not apply the product on newly seeded grass as it may inhibit seeds from germinating, wait until after first mowing when root systems are established.
- If over-seeding or re-sodding in the spring, do not apply the product.
- If over-seeding or re-sodding in the fall, do not apply the product.
- Not recommended for use with a fertilizer containing nitrogen.
- Apply the product to dry or moist soil.
- Do not apply to excessively saturated soil.
- Do not apply if rain is forecasted within 24 hours after application.
- Do not water lawn for 24 hours after application.
- Excessive moisture at the time of application may reduce the effectiveness of the product.

1.4 Mode of Action

The mode of action of liquid corn gluten is to prevent the normal development of roots by releasing organic dipeptides into the soil and inhibiting root formation of germinating seeds. Liquid corn gluten does not prevent seed germination or affect the root systems of mature plants but rather causes seedlings with less than normal root systems to succumb to dehydration when exposed to drought stress.

Five dipeptides, glutaminyl-glutamine (Gln-Gln), alaninyl-asparagine (Ala-Asn), alaninyl-glutamine (Ala Gln), glycinyl-alanine (Gly-Ala) and alaninyl-alanine (Ala-Ala) and a pentapeptide, leucine-serine-proline-alanine-glutamine (Leu-Ser-Pro-Ala-Gln) were identified as the active components of liquid corn gluten.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient & Method for Formulation Analysis

The applicant uses the Corn Products International Corn products of America Standard Methods of Analyses (CPSMA) Methodology for measurements of protein content, which is equivalent to the "Corn Refiners Association methodology and the Association of Official Analytical Chemists (AOAC) method.

3.0 Impact on Human and Animal Health

3.1 Integrated Toxicological Summary

No toxicological studies were submitted for the active ingredient, Liquid Corn Gluten Manufacturing Concentrate, and the associated end-use product, TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer. Published literature and Material Safety Data Sheets (MSDSs) were submitted to support requests to waive all toxicology data requirements. The provided information and additional information collected by the PMRA from available published sources on health effects of corn gluten meal were utilized to assess human health risks.

The applicant requested data waivers for toxicity and irritation studies on the following basis: 1) corn gluten meal, CGM, is a by product of the wet milling process for production of maize starch and is predominantly used in the animal feed industry; 2) hydrolyzed corn gluten derived from the proteolytic enzymatic treatment does not pose any acute oral risks as it is frequently used in the food and cosmetic industries; 3) the hydrolyzation of corn gluten protein results in an equally benign material; 4) the MSDS for hydrolyzed corn protein shows no concerns for toxicity, it is considered to be non-toxic at chronic and subchronic levels, and is not expected to be carcinogenic.

The submitted waiver rationales were accepted on the basis that: 1) information on corn gluten meal indicates no concern for toxicity; 2) the enzyme used for hydrolyzation is widely used in food industry and is widely regarded as safe; 3) hydrolyzed corn gluten is used in food and cosmetic industries without any reported adverse effects.

An assessment of the human health impacts of liquid corn gluten was based on information available on corn gluten meal. The most common adverse effect reported in humans for corn and corn by-products in the published literature is allergy. Symptoms include dermal reactions, respiratory ailments, gastrointestinal difficulties and severe anaphylaxis. Adverse effects were also reported for corn dusts. However, these effects are limited mainly to grain and feed workers who are exposed to these dusts in enclosed spaces on a daily basis. In addition, the cause of these reactions is still debated as corn and other grain dusts may contain numerous bacterial and fungal contaminants which can induce allergic and/or toxic reactions. Many of the fungi that grow on raw corn produce mycotoxins that may not be removed during wet-milling. Therefore, feed-grade corn gluten meal may also contain contaminating species of fungi particularly from

the genus *Fusarium* and/or their associated mycotoxins, including fumonisins (B1, B2, B3), trichothecenes (types A and B), zearalenone, aflatoxin and ochratoxin A. The amount of these mycotoxins present in feed-grade corn gluten meal is regulated by the Canadian Food Inspection Agency (CFIA). Currently, aflatoxin is the only mycotoxin regulated in the *Feeds Act* and Regulations, however recommended tolerance levels have been established for many of the remaining groups of mycotoxins.

Based on the submitted and available information for hydrolyzed corn gluten and corn gluten meal, liquid corn gluten is expected to be of low acute toxicity via the oral, dermal and pulmonary routes, minimally irritating to the skin, and mildly irritating to the eyes if it conforms to the mycotoxin guidelines established by the CFIA. Therefore, it is required that the mycotoxin levels present in both the manufacturing concentrate and end-use product do not exceed the tolerance levels established by the CFIA for feed. In addition, liquid corn gluten is also expected to be a potential sensitizer as corn gluten meal is classified as a potential sensitizer and the active ingredient is derived from corn gluten meal using a microbial enzyme.

Since the active ingredient is processed from corn gluten meal, which is a byproduct of the wet milling of corn, it is unlikely that liquid corn gluten is carcinogenic, genotoxic, neurotoxic, and/or a developmental/reproductive toxicant. The enzymatic break down products of corn gluten meal, using a proteolytic enzyme which is widely used in food industry, are not likely to be of toxicological concern if both the manufacturing concentrate and associated end-use product are used according to label directions. Therefore, short-term toxicity, prenatal developmental toxicity, and genotoxicity data requirements for liquid corn gluten were waived by PMRA.

3.2 Food Residue Exposure Assessment

A food residue exposure assessment was not conducted by PMRA as the accepted uses for TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer do not include application to food crops.

3.3 Residential Risk Assessment

3.3.1 Use Description

The end-use product is for a herbicidal use (USC 30) on residential lawns, where established perennial rye grass and Kentucky blue grass are predominant, for inhibiting dandelion, crab grass, and clover seed germination. It is to be applied with a hand-held or backpack sprayer or a hose end sprayer at a rate of 1.08 L/100 m^2. The amount of active ingredient for 100 m^2 is calculated as 1.25 kg (125 kg a.i./ha). The maximum application rate is 3 L/100 m^2 (3.75 kg a.i./100 m^2 or 375 kg a.i./ha). The product is packaged as 1 L, 2 L, 4 L, 5 L and 10 L containers. Except the 10 L container, every other container has an integrated applicator, which is to be attached to a hose before spraying. The 1 L, 2 L, 4 L, and 5 L containers are calibrated to treat 93 m^2 (1,000 ft^2), 186 m^2 (2,000 ft^2), 372 m^2 (4,000 ft^2), 465 m^2 (5,000 ft^2), respectively. Loading and mixing is required only for the 10 L container. For application, the

product is to be loaded and mixed with water at a ratio of 1:3 and sprayed with a hand-held or back pack sprayer. The 10 L container will treat 930 m^2 (1,000 ft^2).

The product is applied in early spring (April to mid-May) and again in late summer (August–September) before weed seeds have germinated. If over-seeding is done in the spring, the product is not to be applied until the fall. If over-seeding is required later in the season, seeding is to be done in mid-August to allow the seed to germinate (10–15 days depending on seed) before applying the product in mid to late September. The maximum number of applications in a year is two.

3.3.2 Residential Exposure and Risk Assessment

Residential exposure to TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer is expected to be of short-term duration and predominantly by the dermal route during handling and application, and from dermal contact of wet treated surfaces. Inhalation of product is possible during loading and mixing of the 10 L package, and also from spray mist during the application, but is likely to be a minor route of exposure. Also, accidental ingestion and ocular exposure to the end-use product are also possible during handling and application, but are likely to be minor routes of exposure.

The end-use product is expected to be of low acute toxicity via the oral, dermal and pulmonary routes, minimally irritating to the skin, mildly irritating to the eyes, and a potential sensitizer. Repeated dermal exposure to the end-use product can result in skin sensitization. The end-use product is unlikely to have any short-term or prenatal developmental effects or genotoxic effects. The proper use and handling of the end-use products, following label directions, is not likely to result in repeated or prolonged human exposure by any routes at a concentration that is likely to raise toxicological concerns.

Although a margin of exposure could not be estimated based on the toxicological information available, exposure to the end-use product when label instructions and precautions are observed is not expected to pose a health concern. As a hygiene measure, the label states that domestic users wear a long-sleeved shirt, long pants, closed foot wear and gloves when handling the product and during application. Also, the label instructs the domestic users to avoid contact of the end use product with the skin, eyes and clothing. It is recommended as a hygiene measure that freshly prepared spray solution must be used each time when applying by a hand-held or back pack sprayer.

3.3.3 Bystander Exposure and Risk Assessment

Bystander exposure (including children and pets) is expected to be negligible when the product is used according to label directions. The end-use product label instructs users to not apply product under windy conditions, thereby limiting bystander exposure from possible spray drift.

3.3.4 Post-Application Exposure

Post-application dermal exposure is possible when adults, children or pets re-enter a recently treated site before residues are dried. Also, exposure from hand-to-mouth contact is of concern should children play on recently treated lawns. Adding a restricted entry statement on the product label permitting entry of adults, children and pets to treated sites only after the spray has dried can mitigate this exposure concern.

It is expected that, due to the relatively low toxicity of the end-use product, the requirement for personal protective equipment (PPE), precautionary and hygiene statements on the product label, risks to domestic users and bystanders are not of concern.

3.4 Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on Health Canada's website. Incidents from Canada were searched and reviewed for active Corn Gluten Meal (COR).

As of February 4, 2011, there have been three human incident reports for products containing corn gluten meal (COR) in Canada which were classified as minor in nature. All of the reports involved domestic class products and two of them are from handling the product. The common effects reported were dermal irritation (2), eye irritation (1) and respiratory congestion not related to product application or handling (1). Although details were limited in these reports, it is evident that products were not used according to label directions. There were 13 incidents reported for animals for products containing corn gluten meal (COR) in Canada, of which nine are classified as minor and four moderate in nature. The most common effects were dermal irritation from dermal exposure, eye irritation from ocular exposure, and vomiting and diarrhea from accidental ingestion of the product.

Although liquid corn gluten is not chemically equivalent to corn gluten meal, information on corn gluten meal was considered in the overall risk assessment for liquid corn gluten. Since the active for the EP is liquid in nature, unlike the solid corn gluten meal, and there is a restricted entry interval to the treated site until surfaces are dried, no adverse effects are expected from the use of liquid corn gluten product when it is used according to label directions.

The PMRA concluded that the information from the incident reports supported the current toxicity database for corn gluten meal; however, it did not impact the risk assessment for liquid corn gluten. Detailed information for the incidents can be found on the PMRA Public Registry.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

When applied to turf, it is anticipated that liquid corn gluten will readily degrade through natural processes and will not persist in its original form. Overall, the chemical process used to solubilize corn gluten meal into liquid corn gluten may result in a greater mobility of this compound in terrestrial and aquatic environments through runoff, when compared to the solid form.

When using corn gluten as a herbicide, it is important to consider that liquid corn gluten will also be releasing nitrogen to the lawn. Biological processes in soil convert nitrogen to various chemical forms. Of particular concern is nitrate, which is highly soluble in water and could contaminate groundwater. Thus, it is important to avoid inadvertently over-loading lawns with nitrogen from multiple sources. Label statements informing users to not use a fertilizer in combination with this herbicide product should alleviate this potential problem.

Also, liquid corn gluten could contribute to nitrogen loading of nearby aquatic systems through runoff. Standard label statements pertaining to run-off should mitigate this concern.

4.2 Effects on Non-Target Species

Corn gluten meal is a naturally occurring substance with a non-toxic mode of action. It has been used for many years as a food source for pets and farm animals, including aquaculture. Thus, liquid corn gluten is not expected to be toxic to terrestrial or aquatic organisms. Based on the use pattern of TurfMaize Bio-Herbicide Corn Gluten Weed Preventer, the exposure of non-target terrestrial and aquatic organisms to liquid corn gluten is expected to be minimal. As a result, environmental risk to terrestrial and aquatic organisms should also be minimal.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer

Information submitted to support the pest claims included a rationale in order to utilize the more substantive efficacy data for corn gluten meal from which liquid corn gluten is derived. The information provided consisted of 2 published seed germination research studies, 1 published greenhouse research study, 2 unpublished field studies and the U.S. Patent for Corn Gluten Hydrolysate (a.k.a. liquid corn gluten). All information was assessed in context with the label claim that the product may inhibit the seed germination of dandelion, crabgrass (smooth and large) and white clover.

5.1.2 Acceptable Efficacy Claims for TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer

Adequate information was submitted to accept the claim that TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer may inhibit the seed germination of dandelion, crabgrass (smooth and large) and white clover when applied as proposed. The pest claims will be confirmed with additional trials requested under the conditions of registration.

The label cautions that any established dandelion, crabgrass (smooth and large) and white clover at the time of application will not be inhibited.

5.1.3 Herbicide Tank Mix Combinations

No tank mixtures with TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer were proposed.

5.2 Phytotoxicity to Host Plants

The same data submitted by the applicant to support the efficacy claims were also considered in the phytotoxicity assessment to host plants.

5.2.1 Acceptable Claims for Host Plants for TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer

No direct evidence was submitted to support the claim that TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer is safe for use on established perennial ryegrass and Kentucky bluegrass under field conditions at the rates proposed. However, in consideration of the following information, established perennial ryegrass and Kentucky bluegrass would not be negatively impacted when TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer is applied in accordance with the use directions on the product label.

- The active ingredient contained in TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer is the hydrolyzed protein of the corn gluten meal that is presently registered in end-use products for use on established perennial ryegrass and Kentucky bluegrass. Based on the use history with corn gluten meal (first registered in 2003), there is reasonable expectation that the same crops presently registered for use with corn gluten meal would also be tolerant to applications of TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer.

- The product should not be applied to newly seeded grass but rather should only be applied to established lawns having a well developed root mass.

5.3 Impact on Succeeding Crops

The impact on succeeding crops is not relevant for a non-conventional pest control product that is applied to turfgrass.

5.4 Economics

No market analysis was assessed for this product review.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, liquid corn gluten was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Liquid corn gluten does not meet the Track 1 criteria and will not form any transformation products which meet the Track 1 criteria. Liquid corn gluten is a hydrolyzed form of a naturally occurring substance (corn meal gluten) and is not expected to be persistent or bioaccumulative in the environment.

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[5] DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Liquid corn gluten and the end-use product TurfMaize Bio-Herbicide Corn Gluten Weed Preventer do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

- The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

Data on the active ingredient was limited; however, information was available on the parent compound (corn gluten meal).

The active ingredient and the associated end-use product are expected to be of low acute toxicity via the oral, dermal and pulmonary routes, minimally irritating to the skin, mildly irritating to the eyes, and a potential sensitizer. The source material for the TGAI is expected to be of food grade quality. Liquid corn gluten is not expected to be carcinogenic, genotoxic, neurotoxic or a developmental/reproductive toxicant.

Because TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer is not to be applied to food or feed, the establishment of a maximum residue limit was not required for liquid corn gluten.

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6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

8 DIR2006-02, *PMRA Formulants Policy*.

The precautionary statements on the product labels are adequate to protect domestic users and bystanders. The product label instructs domestic users to not apply TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer if a member of the household has a sensitivity or allergy to corn and to not apply product under windy conditions. Furthermore, restricting entry to treated sites until lawns are dried will minimize exposure of adults, children and pets to liquid corn gluten. Residential exposure to the end-use product is expected to be minimal if the precautionary statements and recommended personal protective equipment on the end-use product label, which are intended to minimize residential exposure, are observed.

7.2 Environmental Risk

Liquid corn gluten is a substance that is produced from corn gluten meal, which occurs naturally in the environment. The exposure of non-target organisms to this substance under operational conditions is considered to be negligible, and it is not expected to cause any adverse effects to the environment.

7.3 Value

The data submitted to register TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer are adequate to describe the end-use product as a pre-emergent dandelion, crabgrass (small and large) and white clover seed germination inhibitor for use on lawns where established perennial ryegrass and Kentucky bluegrass are the predominant grass species.

7.4 Unsupported Uses

There were no unsupported uses.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Liquid Corn Gluten Manufacturing Concentrate and TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer containing the active ingredient Liquid Corn Gluten, as a pre-emergent dandelion, crabgrass (smooth and large) and white clover seed germination inhibitor for use on lawns where established perennial ryegrass and Kentucky bluegrass are the predominant grass when used in conjunction with a sound lawn maintenance program.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

a.i.	active ingredient
aka	also known as
CAS	Chemical Abstracts Service
cm	centimetres
DACO	data code
EP	end-use product
g	gram
ha	hectare(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
km	kilometre
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*-octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOEC	low observed effect concentration
LR_{50}	lethal rate 50%
m	metre
m^2	square metres
mg	milligram
mL	millilitre
MOE	margin of exposure
MRL	maximum residue limit
N/A	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
N/R	not required
NZW	New Zealand white
pK_a	dissociation constant
PCPA	*Pest Control Product Act*
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
REI	restricted-entry interval
RSD	relative standard deviation
$t_{1/2}$	half-life
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Toxicity profile of liquid Corn Gluten (96.71%)

Study Type	Data Waiver Requests	Comment	Reference
Acute toxicity: Oral, Dermal, and Inhalation	Waiver rationale: Used in the food and cosmetic industries. The hydrolyzation of corn gluten protein results in an equally benign material. MSDS indicates no acute toxicity. Hydrolyzed corn gluten is used in food and cosmetic industries without any reported toxicological adverse effects. Waiver accepted	Low acute toxicity May cause respiratory irritation based on the nature of the active ingredient mixture containing chemical stabilizers.	1806164
Skin irritation	Waiver rationale: No dermal irritation risks due to its frequent use in the food and cosmetic industries and not expected to be irritating to the skin as indicated in the MSDS. The waiver is accepted with reservation. The TGAI is considered to be minimally irritating to the skin.	Minimally irritating to skin. MSDS has skin protection recommended: Wear impermeable gloves and protective clothing. Moreover, there is irritation concern from the chemicals used during processing or added to the active ingredient as stabilizers as they have irritation potential.	1806164
Eye irritation	Waiver rationale: MSDS indicates that ocular exposure is likely to cause transient redness if not washed out and left in the eye for an extended period of time. No corneal involvement or visual impairment is expected. Waiver accepted	Mildly irritating MSDS requires eye protection: safety glasses with side shields. Also, there is concern from the chemicals used during processing or added to the active ingredient as stabilizers as they have irritation potential.	1806164
Sensitization	Waiver rationale: MSDS indicates that this material is not known or reported to be a skin or respiratory sensitizer. The waiver is accepted with reservation. The active ingredient is considered to be a potential sensitizer.	Potential sensitizer Corn gluten is classified as a potential sensitizer, and there are no studies done to indicate that hydrolyzed corn gluten is not a sensitizer. Moreover, the microbial enzyme used in the processing is an impurity and the active ingredient is a mixture which contains chemicals added as stabilizers or residues from processing stages.	1806164

Table 2 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Applicant proposed label claims	Accepted label claims	Unsupported label claims
Applic. rate & timing: i) early spring at 1.08 L/100m^2 (1.25 kg a.i./100m^2), & ii) late summer/early fall (after heat stress has passed) at 1.08 L/100m^2 (1.25 kg a.i./100m^2)	- accepted as proposed	
Pest claims: - may inhibit dandelion, crabgrass and clover seed germination.	- may inhibit dandelion, crabgrass (small and large) and white clover seed germination. Additional information to be submitted as a condition of registration to confirm pest claims under field conditions.	
Host claims: - in lawns where established perennial ryegrass and Kentucky bluegrass are the predominant grass species.	- accepted as proposed	
Misc. statements: - inhibitory effect of the product to weed seeds generally dissipates in 4 weeks following application.		- statement not supported by evidence and therefore removed from the label.
- do not apply the product on newly seeded grass as it may inhibit seeds from germinating, wait until after first mowing when root systems are established.	- accepted as proposed	
- if over-seeding or re-sodding in the spring, do not apply the product in the spring.	- accepted as proposed	
- if over-seeding or re-sodding in the fall, do not apply the product in the fall.	- accepted as proposed	
- not recommended for use with a fertilizer containing nitrogen.	- accepted as proposed	

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number: 1688469
Reference: 2008, Chemistry Requirements Liquid Corn Gluten Manufacturing Concentate, Data Numbering Code: 3.0 Confidential Business Information

PMRA Document Number: 1688505
Reference: 2008, Chemistry Requirements- Ep, Data Numbering Code: 3.0 Confidential Business Information

PMRA Document Number: 1856870
Reference: 2009, Batch Data For Corn Gluten, Data Numbering Code: 2.13.3 Confidential Business Information

PMRA Document Number: 1806166
Reference: 2009, Data Numbering Code 2 - Chemistry Requirements For The Registration Of TGAIs, Data Numbering Code: 2.0,2.1,2.11,2.11.1,2.11.2,2.11.3,2.2,2.3,2.3.1,2.4,2.6 Confidential Business Information

PMRA Document Number: 1806121
Reference: 2009, Data Numbering Code 3 Chemistry Requirements For The Registration Of End-Use Product, Data Numbering Code: 3.1.2,3.5 Confidential Business Information

2.0 Human and Animal Health

PMRA Document Number: 1806167
Reference: 1980, Enzymatically Hydrolyzed Protein, Data Numbering Code: 4.2.9

PMRA Document Number: 1806173
Reference: 1989, Enzymatic Hydrolysis Of Corn Gluten Meal, Data Numbering Code: 4.2.9

PMRA Document Number: 1806175
Reference: 2000, Enzymatic Protein Hydrolysates In Human Nutrition, Data Numbering Code: 4.2.9

PMRA Document Number: 1806161
Reference: 2006, Corn Pro 35 Msds, Data Numbering Code: 0.9.1

PMRA Document Number: 1806163
Reference: 2006, Corn Pro 35 Msds, Data Numbering Code: 4.2.9

PMRA Document Number: 1831461
Reference: 2008, Acetic Acid 92% Msds, Data Numbering Code: 0.9

PMRA Document Number: 1831467
Reference: 2008, Dow Chemical Sales Specification Propylene Glycol, Data Numbering Code: 0.14

PMRA Document Number: 1831466
Reference: 2008, Safety Data Sheet Protex 6l, Data Numbering Code: 0.9.1

PMRA Document Number: 1806168
Reference: 2009, Debittering Of Corn Gluten Hydrolysate With Active Carbon, Data Numbering Code: 4.2.9

PMRA Document Number: 1831464
Reference: 2009, Product Specification-ps A01424-2.0en, Data Numbering Code: 0.14

PMRA Document Number: 1831463
Reference: 2009, Safety Of Protex 6l For Use In Manfucture Of Pesticide, Data Numbering Code: 0.8.1

PMRA Document Number: 1806176
Reference: Adie Mannheim And Munir Cheryan, 1992, Enzyme-modified Proteins From Corn Gluten Meal: Preparation And Functional Properties, Data Numbering Code: 4.2.9

PMRA Document Number: 1806156
Reference: Carbohydrase And Protease, Mixture From Bacillus Licheniformis, Data Numbering Code: 4.2.9

PMRA Document Number: 1806158
Reference: Cfr - Code Of Federal Regulations Title 21:, Data Numbering Code: 4.2.9

PMRA Document Number: 1806159
Reference: Cfr - Code Of Federal Regulations Title 21:, Data Numbering Code: 4.2.9

PMRA Document Number: 1806164
Reference: Data Numbering Code 4 Toxicology Requirements For The Registration Of TGAI, Data Numbering Code: 4.2,4.2.1,4.2.2,4.2.3,4.2.4,4.2.5,4.2.6

PMRA Document Number: 1806187
Reference: Rishi Shukla, Munir Cheryan, 2000, Zein: The Industrial Protein From Corn, Data Numbering Code: 4.2.9

PMRA Document Number: 1806179
Reference: Skin Deeps Cosmetic Safety Database, Hydrolyzed Corn Protein, Data Numbering Code: 4.2.9

PMRA Document Number: 1806178
Reference: U. S. Food And Drug Administration, 2001, Agency Response Letter Gras Notice No. Grn 000072, Data Numbering Code: 4.2.9

PMRA Document Number: 1806180
Reference: Zowa S. Olemps, Robert I. Merker, Mary D. Ditto, Michael J. Dinovi, 2006, Food-processing Enzymes From Recombinant Microorganisms¿¿¿a Review, Data Numbering Code: 4.2.9

3.0 Environment

PMRA Document Number: 1806120
Reference: 2009, Data Numbering Code 9 Environmental Toxicology End Product, Data Numbering Code: 9.1

PMRA Document Number: 1806165
Reference: 2009, Data Numbering Code 9 Environmental Toxicology, Data Numbering Code: 9.1,9.3.2,9.3.4,9.4.2,9.5.2.1,9.5.2.2,9.5.2.3,9.5.2.4,9.6.2.1,9.6.2.2,9.6.2.3,9.6.2.4,9.6.2.5,9.6.2.6,9.8.4

4.0 Value

PMRA Document Number: 1806122
Reference: Comprehensive Data Summary Data Numbering Code 10 Value, Data Numbering Code: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.3,10.3,10.3.2

PMRA Document Number: 1869095
Reference: 2006, TurfMaize Pre-emergent Weed Seed Germination Inhibitor With Corn Gluten Trial, Data Numbering Code: 10.6

PMRA Document Number: 2021861
Reference: 2011, Efficacy Of Corn Gluten Meal And Hydrolyzed Corn Gluten Meal As A Means Of Weed Control And Its Effect On Turf Establishment, Data Numbering Code: 10.2.3.3(a)

PMRA Document Number: 1806137
Reference: Dianna Lan-ying Liu And Nick E. Christians, 1994, Isolation And Identification Of Root-inhibiting Compounds From Corn Gluten Hydrolysate, Data Numbering Code: 10.6

PMRA Document Number: 1806140
Reference: Dianna Lan-ying Liu And Nick E. Christians, 1994, United States Patent: 5,920,757: Preemergence Weed Control Using Dipeptides From Cgh, Data Numbering Code: 10.6

PMRA Document Number: 1806134
Reference: Dianna Lan-ying Liu, Nick E. Christians, And John T. Garbutt, 1994, Herbicidal Activity Of Hydrolyzed Corn Gluten Meal On Three Grass Species Under Controlled Environments, Data Numbering Code: 10.6

PMRA Document Number: 1806136
Reference: Dianna Lan-ying Liu, Nick E. Christians, Inhibitory Activity Of Corn Gluten Hydrolysate On Monocotyledonous And Dicotyledonous Species, Data Numbering Code: 10.6

B. Additional Information Considered

i) Published Information

1.0 Environment

PMRA Document Number: 1806132
Reference: EPA, 2006, Exemption of Certain Pesticide Substances From Federal Insecticide, Fungicide, and Rodenticide Act Requirements, DACO: 9.9

PMRA Document Number: 1932179
Reference: Biopesticides Registration Action Document. Glutens, corn (Corn Cluten Meal) (PC Code 100137)., DACO: 12.5

PMRA Document Number: 1947298
Reference: Lan-Ying Liu, D., Christinas, N.E., Garbutt, J.F., 1994, Herbicidal Activity of Hydrolyzed Corn Gluten Meal on Three Grass Species under Controlled Environments, J Plant Growth Regul (1994) 13:221-226 Journal of, DACO: 12.5

2.0 Human Health

Reference: Regulatory proposal REG2003-09. 2003. Corn Gluten Meal.

Reference: United States Environment Protection Agency, Pesticides, Corn Gluten (100137) Fact Sheet:
http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_100137.htm

Reference: Department of Health and Ageing NICNAS, Priority Existing Chemical Assessment Reports – 'Savinase' – a proteolytic enzyme:
http://www.nicnas.gov.au/publications/car/pec/pec2/summary_report.asp

Reference: Human and Environment Risk Assessment on ingredients of household cleaning products, Subtilisins (Protease): http://www.heraproject.com/files/22-F-07_PROTEASE_HERA_Final%20Edition%20(unsecured%20-%20PDFA-1b).pdf

ii) Unpublished Information

1.0 Environment

PMRA Document Number: 1754936
Reference: Incident Report, DACO 0.1.7003

PMRA Document Number: 1754937
Reference: Incident Report, DACO 0.1.7003

PMRA Document Number: 1756500
Reference: Incident Report, DACO 0.1.7003

PMRA Document Number: 1756599
Reference: Incident Report, DACO 0.1.7003

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PMRA Document Number: 1906647
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PMRA Document Number: 1913367
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PMRA Document Number: 1926515
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PMRA Document Number: 1987520
Reference: Incident Report, DACO 0.1.7003